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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------|------------------|
| 10/600,182 | 06/20/2003 | Fritz H. Bach | 13681-012001 | 8996 |
| 26161 | 7590 | 04/19/2006 | EXAMINER | |
| FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022 | | | JONES, DAMERON LEVEST | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1618 | | |

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/600,182 | BACH ET AL. | |
| | Examiner | Art Unit | |
| | D. L. Jones | 1618 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 July 2005 and 29 October 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 and 21-23 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 16-20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>7/13/05 & 10/29/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

APPLICANT'S INVENTION

1. Applicant's invention is directed to methods of using nitric oxide in combination with various other compounds for inflammation, transplantation, cancer, and angioplasty.

Note: Claims 1-23 are pending.

RESPONSE TO APPLICANT'S ELECTION

2. Applicant's election with traverse of Group 33 filed 1/24/06 is acknowledged. In summary, the traversal is on the grounds that (1) the inventions (i.e., Groups 32-41) are closely related since they involve administering nitric oxide. (2) The same body of literature will be searched for all the claims. (3) One would expect similar or at least overlapping search terms to be used for the searches of each invention. (4) A search for methods of transplantation that include administering a pharmaceutical composition comprising nitric oxide would likely find literature describing nitric oxide in combination with a second treatment. Thus, there would seem to be no undue burden on the Examiner to search the full scope of the claims. This is found non-persuasive for reasons of record in the office action mailed 7/25/05. While Applicant asserts (1) – (4) above, it should be noted that the second treatment according to the claims as written involves administering structural different and distinct compounds (e.g., HO-1, carbon monoxide, bilirubin, biliverdin, ferritin, iron desferoxamine, salicylaldehyde isonicotinoyl hydrazone, iron dextran, and apoferritin) having chemically unique

properties to a subject wherein the compound may induce HO-1, resulting in the expressing of HO-1, induce apoferritin, or resulting in the expression of apoferritin. Thus, it would be a burden on the Examiner to search the various second treatment combinations with nitric oxide since the compounds used in the second treatments are not obvious over one another, prior art cited against one compound would neither anticipate nor render obvious all the other compounds of the second treatment. Hence, the restriction requirement is still deemed proper and is therefore made FINAL.

WITHDRAWN CLAIMS

3. Claims 1-15 and 21-23 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

DOUBLE PATENTING REJECTIONS

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 16-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, and 8-13 of copending Application No. 10/177,930. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a method of transplanting an organ by administering a composition comprising carbon monoxide. The claims differ in that those of the instant invention (Applicant's elected invention) require the administration of carbon monoxide in combination with nitric oxide whereas 10/177,930 only discloses that a carbon

monoxide composition is utilized. However, a skilled practitioner in the art would recognize that the method of 10/177,930 uses the term 'comprising' in its method steps that allow for additional method steps to be present. Thus, one may have another administration step (i.e., administration of nitric oxide) which would be obvious since nitric oxide is a highly reactive free radical compound produced by many cells of the body that relaxes vascular smooth muscle (see the background of the instant invention).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

COMMENTS/NOTES

6. It should be noted that no prior art has been cited against Applicant's elected invention. However, Applicant MUST address and overcome the double patenting rejection above. Specifically, the elected invention is distinguished over the prior art of record because the prior art neither anticipates nor renders obvious methods of transplantation as set forth in claims 16-20 wherein nitric oxide is administered in combination with carbon monoxide as set forth in the method steps of the claims.

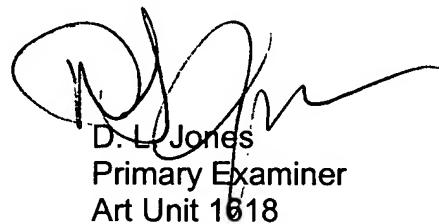
7. Applicant is respectfully requested to cancel the non-elected subject matter.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones
Primary Examiner
Art Unit 1618

April 17, 2006